

**COMMITTEE ON PESTICIDES, CHEMICAL
REGULATION & RIGHT-TO-KNOW COMMITTEE**

***TSCA REFORM LEGISLATION
UPDATE AND PRIMER***

TSCA AMENDMENTS OF 2016

JUNE 28, 2016

WELCOME & INTRODUCTIONS

Moderator: Larry Culleen, Partner, Arnold & Porter LLP

Honored Guest: Jim Jones, Assistant Administrator, US EPA

Featured Panelists:

Alex Dunn, Executive Director & General Counsel, Environmental Council of the States

Mike Walls, VP Regulatory & Technical Affairs, American Chemistry Council

Richard Denison, Lead Senior Scientist, Environmental Defense Fund

Ernie Rosenberg, President & CEO, American Cleaning Institute

Lynn Bergeson, Managing Partner, Bergeson & Campbell, P.C.

Keith Matthews, Counsel, Sidley Austin LLP

REVIEW OF MEETING AGENDA

Remarks of EPA Assistant Administrator (Jim Jones)

Tutorial on Significant Sections

- Section 4 – Testing (Lynn Bergeson)
- Section 5 – Manufacturing and New Uses (Lynn Bergeson)
- Section 6 – Prioritization, Risk Evaluation/Management (Richard Denison)
- Section 8 – Inventory (Keith Matthews)
- Section 14 – Confidentiality (Keith Matthews)
- Section 18 – State – Federal Relationship (Alex Dunn)
- Section 26 – Administration, Fees, Policies and Guidance (Mike Walls)

Round Up of Important Points of View

- Environmental Interest Groups (Richard Denison, EDF)
- State Agencies (Alex Dunn, ECOS)
- Manufacturers (Mike Walls, ACC)
- Processors and Formulators (Ernie Rosenberg, ACI)

Open Discussion and Q&A

STATUS OF TSCA AMENDMENTS

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

- **House of Representatives voted 403 – 12; May 24**
- **Senate passed bill by unanimous consent; June 7**
- **Signed by President Obama on June 22, 2016**

TUTORIAL

§4. TESTING

Expands EPA authority to require development of information

- Authorizes administrative orders and consent agreements in addition to rule making
- Permits EPA to require testing needed for prioritization
- New authority does not require EPA findings
- May not be used to establish “a minimum information requirement of broader applicability”

New Section 4(h) concerns vertebrate animal testing and requires EPA to:

- Reduce and replace such testing to extent practicable, scientifically justified, and consistent with policies of diminished animal testing
- Develop, within 2 years of enactment, and implement a strategic plan to promote alternative test methods

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§5. NEW CHEMICALS/SIGNIFICANT NEW USES

- Retains certain basic requirements
90-day review period, extensions permitted
- Requires EPA determination on all Notices
- Three alternative determinations:
 - NC/SNU presents an unreasonable risk
 - Available information is insufficient **or** NC/SNU may present unreasonable risk **or** NC/SNU chemical has substantial production and exposure, or
 - NC/SNU not likely to present unreasonable risk

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§5. NEW CHEMICALS/SIGNIFICANT

NEW USES (CONT'D)

- **EPA required to regulate under 1 and 2**
- **Limits ability to regulate articles/category of articles compared to prior TSCA, but**
- **Requires EPA also to apply a SNU rule under 1 and 2 or “make public” a statement explaining its findings, the publication of which in the *Federal Register* is not a prerequisite to manufacturing or processing**

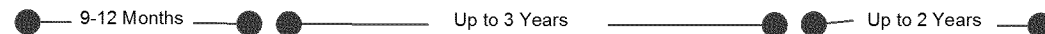
How the Lautenberg Act works

Existing Chemicals



Finding the ways that work

Enforceable Deadlines (can be extended up to 2 more years)



Prioritization

Determination

Risk Management

85,000 chemicals on TSCA Inventory



Inventory "reset": EPA identifies active, inactive chemicals



High Priority
May present an unreasonable risk due to potential hazard and exposure path
EPA to designate at least 20 by 3.5 years

Low Priority
Is not high-priority; can be judicially challenged
EPA to designate at least 20 by 3.5 years

Not enough information
Request/require testing (can extend deadline by 90 days)
If information still insufficient, becomes high-priority

First 10 Work Plan chemicals
• Designate w/in 6 mos
• Not preemptive until final EPA action

Company-requested
• Specific criteria
• ≤ 50% of number EPA initiates
• Company pays full cost (50% if drawn from Work Plan)
• Not preemptive until final EPA action

Risk Evaluation
EPA must establish scope within 6 months



Does present unreasonable risk

Does not present unreasonable risk

Not enough information If information is insufficient or more is needed, can require testing and issue an order to get additional data

EPA must impose prohibitions or restrictions by rule necessary to eliminate the risk; cost used to select among options

EPA imposes full ban of one or more uses; must also consider availability of viable, safer alternatives

Preemption Triggered

During EPA review (3.5 years maximum)
New state restrictions on high-priority chemicals are prohibited except via waiver
Existing state actions remain in effect
Only applies to uses, risks within scope of EPA's review. States can readily get waiver if basic criteria are met or if action was proposed before review began.

After final EPA action (either no unreasonable risk or regulation if risk found)
State restrictions on production, distribution, processing or use taken after 4/22/16 are generally preempted if they apply to the same use/risk EPA addressed. Other state actions (e.g., reporting or disclosure remain in effect or can be taken. States can seek waiver.

- Safety standard:** "No unreasonable risk to human health or the environment."
- Based solely on risks to health/environment
 - EPA cannot consider costs
 - Eliminates "least burdensome" requirement

Key

- = main process steps
- = final agency action
- = interim info-collecting step



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§6. PRIORITIZATION, RISK EVALUATION, RISK MANAGEMENT OF EXISTING CHEMICALS

- Adds prioritization
- Includes timelines
- Specifies minimum number of cases
- Prioritization applies risk-based screening process to designate high- versus low-priorities
 - High-priority: *May present* an unreasonable risk because of a *potential hazard* and a *potential exposure*
 - Low-priority: Does not meet this standard
- Where information is insufficient to support low-priority, default decision is high-priority
- Specifies high-priority categories

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§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- Risk Evaluation process determines whether chemical *presents* an unreasonable risk
- Chemicals found to present unreasonable risk must proceed to EPA risk management action
- Determinations regarding low-priorities and substances that do not present an unreasonable risk can be subject to judicial challenge
- [§9.] Retains EPA mandate to refer risks to another agency in certain cases – but adds mandate for EPA to address risk if other agency does not take timely action

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§6. PRIORITIZATION, RISK EVALUATION, AND RISK MANAGEMENT OF EXISTING CHEMICALS (CONT'D)

- For chemicals that present an unreasonable risk, EPA is required to take timely risk management action
- TSCA's "least burdensome" language deleted; simplified procedural requirements
- EPA must consider/publish statement on certain cost-benefit aspects
- When EPA prohibits one or more uses, EPA also must consider availability of *technically and economically feasible alternatives*
- Allows for exemptions if certain requirements can be met
- Final §6 rules and associated risk evaluations can be subject to judicial review

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INFORMATION GATHERING AND CBI

§8. Reporting and Retention of Information

- **Requires continued use of certain nomenclatures**
- **Inventory “reset:”**

Within 1 year, EPA must promulgate a rule requiring manufacturers (processors) to notify EPA of each chemical substance on the Inventory that has been manufactured or processed during the preceding 10 year period.

- Chemical substances for which notifications are received are to be designated as active.
- Chemical substances for which no notices are received are to be designated as inactive.
- Status of *inactive* chemicals can be changed by notice to EPA
- EPA to review and approve/deny CBI claims made for chemical identity
- **EPA to maintain confidential and non-confidential portions of Inventory**

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INFORMATION GATHERING AND CBI (CON'T)

§14. Confidential Information

Revises and replaces TSCA Section 14

- New section considers *information not protected from disclosure*, including that on:
- Banned or phased-out chemicals, with certain limitations
- Health and safety studies
 - “does not authorize the disclosure of any information, including formulas (including molecular formulas (including molecular structures) of a chemical..., that discloses processes used...or, in the case of a mixture,... the portion of the mixture comprised by any of the chemical substances in the mixture”
- 10 year limitation on CBI protection, subject to renewals
- Requires assertion and substantiation of most CBI claims
- Identifies exceptions to disclosure protections

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§ 18. STATE-FEDERAL RELATIONSHIP

- **Preemption was one of the most debated aspects of TSCA reform.**
- **Grandfathers:**
 - States & local chemical restrictions in place before April 22nd, 2016
 - State laws in place before August 31st, 2003 (e.g. Proposition 65)
- **States are prohibited from establishing or continuing to enforce statutes, regulations, etc., that:**
 - Prohibit or restrict a chemical after EPA has determined that a chemical does not present an unreasonable risk or issued a final §6(a) rule, or
 - Subject a chemical to the same notification of use already established in §5 SNU rule.

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§ 18. STATE-FEDERAL RELATIONSHIP

- **Two Types of Preemption:**
 - Permanent – occurs once EPA determines that a chemical does not pose an unreasonable risk, or issues a rule.
 - Pause – temporary and occurs when EPA is in midst of conducting risk evaluation.
- **Two Types of Corresponding Waivers:**
 - “Discretionary exemptions” from permanent preemption.
 - “Required exemptions” from pause preemption.
- **Preemption does not affect state or federal common law rights and private remedies (e.g. tort actions).**

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§ 18. STATE-FEDERAL RELATIONSHIP

- **Exceptions: Past and future actions are *not* preempted when the state action:**
 - Implements a “reporting, monitoring, disclosure, or other information” obligation
 - Is adopted under the authority of another federal law.
 - Under certain circumstances, is adopted under a state law related to water quality, air quality, or waste management.
 - Is identical to a requirement prescribed by EPA
- ***Key Point:***
No preemption on new and any other chemicals EPA is *not* currently studying or acting on.

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§26. ADMINISTRATION AND FEES

- **Expands EPA's authority to collect fees to defray costs subject to certain limitations**
 - Applies to manufacturers and processors
 - Fee rule developed in consultation with industry
 - Fund and accountability provisions
- **Requires EPA to:**
 - Use the best available science and weight of evidence
 - Develop needed policies, procedures, and guidance (PP&G)
 - Establish Science Advisory Committee on Chemicals (SACC)

ROUND UP OF IMPORTANT POINTS OF VIEW

- Agency (Jim Jones, AA, OCSPP)
- Environmental Interest Groups (Richard Denison, EDF)
- State Agencies (Alex Dunn, ECOS)
- Manufacturers (Mike Walls, ACC)
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OPEN DISCUSSION

QUESTION & ANSWER SESSION

BACKGROUND RESOURCES OF INTEREST

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

<http://www.ecos.org/documents/lautenberg-chemical-safety-act-state-issues-comparison-table/>

<http://blogs.edf.org/health/2016/06/13/resources-for-understanding-the-lautenberg-act/>

<http://www.tscablog.com/>

<http://www.arnoldporter.com/~media/files/perspectives/publications/2016/05/the-tsca-amendments-simplified-nine-key-features-of-the-new-law-and-three.pdf>